

**Defendant.**

**OPPOSED**

**PLAINTIFF EDWIN R. BANK'S MOTION FOR SUMMARY JUDGMENT  
AND BRIEF IN SUPPORT THEREOF**

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COMES NOW Plaintiff Edwin R. Banks (“Mr. Banks”), and pursuant to Rule 56 of the Federal Rules of Civil Procedure, moves for summary judgment that the Defendant Alex M. Azar, II, in his official capacity of the U.S. Department of Health and Human Services (the “Secretary”) is collaterally estopped to deny that tumor treatment field therapy (TTFT) is a Medicare covered benefit/is “medically reasonable and necessary” for Mr. Banks. Because the Secretary is collaterally estopped to deny these facts/conclusions, summary judgment should be granted that Mr. Bank’s claim for TTFT coverage is approved. This motion is based upon the pleadings of record, relevant legal authorities, and the Declaration of James Pistorino, attached hereto as Exhibit A.

## **I. NARRATIVE SUMMARY OF UNDISPUTED FACTS**

1. The Center for Medicare & Medicaid Services (CMS) has designated the Administrative Qualified Independent Contractor (AdQIC) as his representative to receive notices of hearings before ALJs of appeals from decisions denying reconsideration. *See* Exhibit A-1, pp. 3-4.

2. The AdQIC relevant to Mr. Banks’s hearing before ALJ Gulin was MAXIMUS. *See* Exhibit A-2, pp. 5-9.

3. On April 17, 2019, MAXIMUS was provided with notice of the hearing related to ALJ Appeal No. 1-8428973391 to be held by ALJ Gulin on May 15, 2019. *See id.*

4. On May 13, 2019, MAXIMUS was provided with notice of the hearing related to ALJ Appeal No. 1-8498071113 to be held by ALJ Gulin on May 15, 2019. *See* Exhibit A-3, pp.10-14.

5. On May 14, 2019, MAXIMUS was provided with notice of the hearing related to ALJ Appeal No. 1-8501252025 to be held by ALJ Gulin on May 15, 2019. *See* Exhibit A-4, pp.15-19.

6. The Secretary did not appear at the hearing held on May 15, 2019, by ALJ Gulin. *See* Exhibit A, p. 2, ¶ 8.

7. Mr. Banks was represented by attorney Debra Parrish at the hearing held on May 15, 2019 by ALJ Gulin. *See* CAR1273.

8. On June 6, 2019, ALJ Jeffery Gulin issued a FULLY FAVORABLE decision covering ALJ Appeal Nos. 1-8498071113, 1-8428973391, and 1-8501252025. *See* CAR1273-80.

9. ALJ Gulin's June 6, 2019 decision relates to Mr. Bank's claim for TTFT coverage for the months of February 2018 and May 2018-January 2019. *See* CAR1280.

10. At issue ALJ Gulin's decision was whether TTFT was a Medicare covered benefit for Mr. Banks. *See* CAR1273, 1277.

11. ALJ Gulin found that TTFT was a Medicare covered benefit for Mr. Banks. *See* CAR1279.

12. At issue in ALJ Gulin's decision was whether TTFT was "medically reasonable and necessary" for Mr. Banks. *See* CAR1273.

13. ALJ Gulin found that TTFT was "medically reasonable and necessary" for Mr. Banks. *See* CAR1279.

14. The Secretary did not appeal ALJ Gulin's decision.

15. ALJ Gulin's June 6, 2019 decision is part of the Record in this case. *See* CAR1273-79.

16. On June 3, 2019, ALJ Bruce Kelton issued an UNFAVORABLE decision in ALJ Appeal No. 1-8136495060. *See* CAR1251-62.

17. ALJ Kelton's June 3, 2019 decision relates to Mr. Bank's claim for TTFT coverage for the months January, March, and April 2018. *See* CAR1251.

18. At issue in ALJ Kelton's decision was whether TTFT was a Medicare covered benefit for Mr. Banks. *See* CAR1252.

19. ALJ Kelton held that TTFT was not a Medicare covered benefit for Mr. Banks. *See* CAR1261.

20. At issue in ALJ Kelton's decision was whether TTFT was "medically reasonable and necessary" for Mr. Banks. *See* CAR1261, 1262.

## **II. LEGAL BACKGROUND**

Collateral estoppel (*i.e.*, "issue preclusion") is a venerable common law doctrine that bars re-litigation of a legal or factual issue determined in a prior

proceeding. Under the doctrine of collateral estoppel, “once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation.” *Montana v. United States*, 440 U.S. 147, 153-54 (1979).

Collateral estoppel serves the triple purposes of protecting litigants from the burden of relitigating an identical issue against the same party, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *See, e.g., Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1978).

In the Eleventh Circuit, collateral estoppel applies if: 1) the issue at stake is identical to the one involved in the prior proceeding; 2) the issue was actually litigated in the prior proceeding; 3) the determination of the issue in the prior litigation must have been a critical and necessary part of the judgment in the first action; and 4) the party against whom estoppel is asserted must have had a full and fair opportunity to litigate the issue in the prior proceeding. *See, e.g., Christo v. Padgett*, 223 F.3d 1324, 1339 (11<sup>th</sup> Cir. 2000). The preliminary inquiry of whether collateral estoppel is available is a legal question. *Matter of McWhorter*, 887 F.2d 1564, 1566 (11<sup>th</sup> Cir. 1989). The actual application of collateral estoppel is an equitable consideration and the party seeking to invoke collateral estoppel bears the burden of proving that the necessary elements have been satisfied. *Id.*

Parallel/concurrent litigation (especially federal/state) is common. Where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect on the other. *See, e.g., Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922). Thus, even a later filed suit that reaches finality first may have preclusive effect in an earlier filed, but still on-going, litigation. For example, in *Chicago, R.I. & P. RY, Co., v. Elder*, 270 U.S. 611 (1926), the Supreme Court held:

Nor is it material that the action proceeding, in which the judgment, set up as an estoppel, is rendered, was brought after the commencement of the action or proceeding in which it is pleaded. ... Whenever a judgment is rendered in one of the courts and pleaded in the other the effect of that judgment is to be determined by the application of the principles of res judicata by the court in which the action is still pending in the orderly exercise of its jurisdiction, as it would determine any other question of fact or law arising in the progress of the case.

*Id.* at 615-16.<sup>1</sup>

Because of the unique posture of the United States as a litigant, the Supreme Court has held that offensive, non-mutual collateral estoppel does not apply against the United States. *See U.S. v. Mendoza*, 464 U.S. 154 (1984). As a result, only a party to a prior proceeding with the government can assert collateral estoppel against

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<sup>1</sup> “Res judicata” is a legal doctrine incorporating the concepts of “claim preclusion” (formerly known as “merger” and “bar”) and “issue preclusion” (formerly known as “collateral estoppel”). The confusing use of these terms has led to modern efforts to limit “res judicata” to mean “claim preclusion” and to use the term “issue preclusion” instead of “collateral estoppel.” *See* THE RESTATEMENT (SECOND) OF JUDGMENTS (1982); *Migra v. Warren City School District Board of Education*, 465 U.S. 75, 77 n. 1 (1984).

the government. Nevertheless, collateral estoppel, even offensive collateral estoppel, may be asserted against the government. *See, e.g., U.S. v. Moser*, 266 U.S. 236 (1924) (government collaterally estopped from contesting that time at the Naval Academy was “service during the civil war”); *Hanover Bank v. U.S.*, 285 F.2d 455, 459-60 (Ct. Cl. 1961) (action for refund of taxes, government estopped from recalculating taxes based on finding in prior litigation between the parties, cited in *U.S. v. Utah Construction Co.*, 384 U.S. 394, 422 (1966)).

Here, Mr. Banks is not seeking to collaterally estop the Secretary with respect to coverage for TTFT claims filed by any person other than himself. Instead, Mr. Banks contends that he should not have to relitigate the same coverage issues against the Secretary that have already been finally and conclusively determined in his favor.

Proceedings giving rise to collateral estoppel are not limited to cases before federal or state courts. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general

matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

(internal citations omitted). *See also B & B Hardware, Inc. v. Hargis Industries, Inc.*, 135 S.Ct. 1293, 1302-3 (2015) (confirming that administrative decisions can be a basis for issue preclusion).

The application of collateral estoppel based on agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Continental Can Co., U.S.A., v. Marshall*, 603 F.2d 590 (7<sup>th</sup> Cir. 1979) (DOL collaterally estopped by prior decisions of department); *Bowen v. United States*, 570 F.2d 1311, 1321-23 (7<sup>th</sup> Cir. 1978) (NTSB acting in judicial capacity in prior proceeding, plaintiff collaterally estopped); *Brewster v. Barnhart*, 145 Fed.App'x. 542 (6<sup>th</sup> Cir. 2005) (SSA ALJ collaterally estopped by prior ALJ' work determination); *Islam v. U.S. D.H.S.*, 136 F.Supp.3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge's determination); *Cannon v. U.S.*, 2019 WL 5550065 at \*4-5 (S.D. Cal. October 28, 2019) (plaintiff collaterally estopped by ALJ decision that became final while district court case was pending).

### **III. FACTUAL BACKGROUND**

Mr. Banks sets forth the following factual background information. While Mr. Banks does not believe that any of the information here is necessary to grant his motion for summary judgment (though the statements herein are supported by the Record), a discussion of the factual context may assist the Court in consideration of the issues.

Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically 3 months. With earlier forms of treatment before TTFT, the survival rate at two years after treatment is ~31%, while at five years, only ~5% of patients are living.

More recently, treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates. Indeed, TTFT has proven so effective that, in late 2014, a

randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT treatment from the control group.<sup>2</sup>

In ground-breaking papers published in the Journal of the American Medical Association (JAMA)<sup>3</sup> in 2015 and 2017, TTFT was shown to increase the 2-year survival rate by more than 38% and to nearly triple the five-year survival rate.<sup>4</sup>

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<sup>2</sup> In much scientific research, study participants are randomly assigned to “control” and “test” groups. The “control” group does not receive the treatment being tested. In contrast, the “test” group does. Proceeding in this way facilitates the determination of which effects, if any, are the result of the tested treatment as opposed to normal variation among the study participants. During the course of a study, interim results are frequently measured to determine whether the study is proceeding as planned and whether any changes are needed. When the interim results indicate that the tested treatment has a significant effect on health or safety, either negative or positive, ethical guidelines dictate that the study should be halted. Thus, if the interim results indicate that the tested treatment was significantly more likely to result in death than the control group, the study would be halted and the treatment no longer given to the “test” group. Likewise, if the interim result indicated that the tested treatment was life-saving, the study would be halted and the treatment would be made available to the “control” group. In those circumstances, withholding the treatment from the “control” group would be unethical.

<sup>3</sup> The Journal of the American Medical Association (JAMA) is widely regarded as one of the most prestigious medical journals in the world.

<sup>4</sup> See *Stupp, et al.*, “MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL”, JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); *Stupp, et al.*, “EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA”, JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

As reported, TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all major private insurers cover TTFT. TTFT extends GBM patients' lives, in some cases, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It has a Level One recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention. Further, TTFT is FDA approved.

The sole supplier of the equipment that delivers TTFT is Novocure, Inc. which manufactures the Optune system. The Optune system is rented on a monthly basis. Once a Medicare patient suffering from GBM is prescribed the Optune system, they will have monthly claims for Medicare coverage. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment will have to continue that treatment for the rest of their lives.

#### **A. The Medicare Appeals Process**

People suffering from GBM and being treated with TTFT will have multiple claims for Medicare coverage. Typically, these claims will be submitted every one to three months to reflect their continued usage of the TTFT device. Each claim for Medicare coverage concerns only the one to three months at issue for that claim.

Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process that can (and typically does) take more than a year. At issue at each stage of the process is whether the claim is a Medicare covered benefit/is medically reasonable and necessary for the beneficiary. The beneficiary begins by submitting a claim. *See* 42 C.F.R. §§ 405.920-928.<sup>5</sup> If the claim is denied, the beneficiary can request “redetermination.” *See* 42 C.F.R. §§ 405.940-958. If the claim is still denied, the beneficiary can request “reconsideration.” *See* 42 C.F.R. §§ 405.960-978.

If the claim is still denied, the Secretary is required to provide “hearings” for appeals to the “same extent” as is provided for in Social Security hearings. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(b)). That is, in conducting the hearings, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence.

The Secretary has promulgated regulations concerning the conduct of the “hearing” by administrative law judges (ALJs). *See* 42 C.F.R. §§ 405.1000-1058. At a minimum, in the case where the beneficiary is represented by counsel, the hearings are adversarial. In such a case, the Secretary’s representative (in the form

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<sup>5</sup> At issue in this case are claims submitted under “Original Medicare” (*i.e.*, “Medicare Part B”). Accordingly, the regulatory citations herein are those applicable to Part B claims. Medicare Part C (*i.e.*, “Medicare Advantage Plans”) are governed by similar/identical regulations. *See* 42 C.F.R. §§ 422.560-626.

of the Centers for Medicare and Medicaid Services (CMS) or a “contractor” to Medicare) has the opportunity to litigate as a party. *See* 42 C.F.R. §§ 405.1008 and 405.1010.

In that capacity, the Secretary (like the beneficiary) can submit evidence (42 C.F.R. § 405.1018), object to the timing of the hearing (42 C.F.R. § 405.1020), object to the issues before the ALJ (42 C.F.R. § 405.1024); object to the assigned ALJ (42 C.F.R. § 405.1026); present evidence in the form of documents and witnesses (including through subpoenas), cross-examine witnesses, and present and argument (42 C.F.R. § 405.1036); and take discovery (42 C.F.R. § 405.1037). After the hearing, the ALJ issues a written decision that includes findings of fact, conclusions of law, and the reasons for the decision and must be based on the evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046.

Like the beneficiary, if the Secretary is dissatisfied with the decision of the ALJ, the Secretary can appeal to the Medicare Appeals Council (“Council”). *See* 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of whether the Secretary chooses to participate in the hearing, the Secretary can appeal an ALJ’s decision on so-called “own motion” review. *See* 42 C.F.R. § 405.1110. In order to be timely, an appeal to the Council (either direct or on “own motion review”) must be made within 60 days of the ALJ’ decision being appealed. *See* 42 C.F.R. § 405.1110(a) and (b)(2).

Finally, if the beneficiary is dissatisfied with a decision from the Council, they can seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(g)).

Although the statutes and regulations require both ALJs and the Council to issue decisions within 90 days, those deadlines are routinely missed. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2). Thus, Medicare beneficiaries seeking coverage are often thrown into a multi-year effort to obtain coverage or at least get a decision on each denied claim before they can seek relief in a federal court.

### **B. Local Coverage Determinations**

Because the relevant decisions contain discussion about “LCDs”, some discussion of what they are may help orient the Court. Much of the Medicare program is not actually run by the Secretary. Instead, the Secretary has divided the country into four regions and hired contractors (“Medicare Administration Contractors”) to run the lower levels of the Medicare program. In this capacity, the MACs themselves develop Local Coverage Policies (LCD) which guide the processing of claims at the initial levels. Thus, MACs develop LCDs applicable to a device or service.

Claims for Medicare coverage (for Part B) are originally submitted to the MAC for the appropriate region and the MAC itself applies any relevant LCD to approve or reject a claim. Likewise, when an appeal of an initial denial (a

“redetermination”) is submitted, that goes to the MAC - who verifies his earlier decision applying the LCD the MAC developed.

If the claim is denied again and appealed (“reconsideration”), the claim is reviewed by a third party (*i.e.*, the “Qualified Independent Contractor” (QIC)). The QIC is not bound to follow the LCD but if it does not, it must explain its decision. *See* 42 C.F.R. § 405.968(b)(2). Likewise, if the claim is appealed from the QIC, neither ALJs nor the Council are bound by LCDs but, if they do not follow an LCD, they must explain their decision. *See* 42 C.F.R. § 405.1062(a).

In the present case, the LCD that is relevant (L34823 which issued in October 2015) excluded all TTFT from coverage as “not medically reasonable and necessary.” Because the LCD was not updated to reflect the dramatic progress in TTFT science, in May 2019, ALJ Scott Anderson determined that the LCD was not supported by substantial evidence. *See* Exhibit A-6, pp. 30-34. Thereafter, the MAC submitted a revised LCD (that is also being challenged) that only applies to dates of service after September 1, 2019. As a result, the original LCD is deemed invalid. *See* 42 C.F.R. §§ 426.420(b); 426.460(b). Accordingly, the LCD that was used to deny coverage of Mr. Bank’s claim has been invalidated. This is a separate reason why the decision at issue denying coverage should be reversed on the merits. Nevertheless, a proper application of collateral estoppel will prevent Mr. Banks and

this Court from having to bear the burden of litigating the same issues again and again.

#### **IV. BRIEF IN SUPPORT OF SUMMARY JUDGMENT**

As a result of the final decision Mr. Banks received from ALJ Gulin, the Secretary is collaterally estopped from denying that TTFT is a Medicare covered benefit for Mr. Banks. Accordingly, summary judgment should be entered ordering the Secretary to cover Mr. Banks's claim.

##### **A. The Court Can Properly Consider Proceedings Related to ALJ Gulin's Decision**

Before turning to the elements of collateral estoppel, addressing an issue that is related to the Record will facilitate the Court's consideration of this Motion. With regard to the action before this Court, 42 U.S.C. § 405(g) (as modified by 42 U.S.C. § 1395ff(b)(1)(A)) provides:

The court shall have the power, to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing [the Secretary] with or without remanding the cause for a rehearing.

Mr. Banks believes that this motion can be granted relying solely on ALJ Gulin's decision itself. In this case, it is beyond dispute that ALJ Gulin's favorable decision itself is part of the Record. *See, e.g.*, CAR1273-1279.

Nevertheless, to avoid any possible doubt, Mr. Banks is submitting materials related to the proceedings resulting in ALJ Gulin's decision. In particular, Mr. Banks is submitting the Notices of Hearing issued by ALJ Gulin and the pre-hearing

brief submitted by Mr. Banks to ALJ Gulin. This Court may properly take judicial notice of the proceedings related to ALJ Gulin’s decision as part of the “pleadings” in this case.

Because of the manner in which it may arise, judicial notice of other proceedings/decisions giving rise to collateral estoppel is common. *See, e.g., Lobo v. Celebrity Cruises, Inc.*, 704 F.3d 882, 892-93 (11<sup>th</sup> Cir. 2013) (judicial notice of entry of judgment in related proceeding supporting collateral estoppel); *Coney v. Smith*, 738 F.2d 1199, 1200 (11<sup>th</sup> Cir. 1984) (judicial notice of state court proceedings supporting collateral estoppel); *Ross v. Meyer*, 741 Fed.Appx. 56, 59 (3<sup>rd</sup> Cir. 2018) (judicial notice of decisions in parallel proceedings).

Thus, Mr. Banks believes that the Court may consider the proceedings before ALJ Gulin as part of the “pleadings” in this case.<sup>6</sup>

### **B. The Issue at Stake is Identical to the One Involved in the Prior Proceeding**

As described by ALJ Kelton, the issue before him was: “Whether Medicare coverage requirements are met of the Electrical Stimulation Cancer Treatment, CPT

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<sup>6</sup> If the Court believes necessary, pursuant to 42 U.S.C. 405(g) (sixth sentence), the Court may also remand this case to the Secretary with instructions to consider the “new evidence” of the proceedings related to ALJ Gulin’s decision. Given the fact that proceedings before the Secretary are often protracted with the Secretary failing to comply with Congress’ mandate to issue decisions within 90 days, Mr. Banks is asking this Court to enter its Order relying solely on ALJ Gulin’s decision, if possible.

code E0766[.]” *See* CAR1252. Whether a device/service is a Medicare covered benefit itself depends on whether the device/service is “medically reasonable and necessary.” Accordingly, ALJ Kelton considered the issue of whether TTFT was “medically reasonable and necessary” for Mr. Banks and held that it was not. *See* CAR1261, 1262 providing:

It is the decision of the undersigned ALJ that the claim for E0766/Electrical Stimulation Cancer Treatment (aka Tumor Treatment Field Therapy (TTFT)), for the date of service of 1/25/2018, 3/12/2018 and 4/12/2018 are not medically reasonable and necessary. Payment is therefore not allowed by Medicare.

The issue considered by ALJ Gulin was: “Whether the Elec Stim Cancer Treatment (E0766) provided to the Beneficiary on the dates of service meet Medicare coverage criteria.” *See* CAR1273. Likewise, ALJ Gulin considered the issue of whether TTFT was “medically reasonable and necessary” for Mr. Banks. *See* CAR1273 (“Where the services provided are medically reasonable and necessary under Section 1682(a)(1)(A) of the Social Security Act (‘Act’) and covered under Medicare.”). Thus, both decisions considered the identical issue of

whether TTFT met Medicare coverage criteria/was “medically reasonable and necessary” (and, therefore, was a covered benefit).<sup>7</sup>

To the extent that the Secretary contends that the issues are different because each decision concerns specific dates of treatment, that is not well founded. As the Supreme Court noted in *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008), issue preclusion bars successive litigation “even if the issue recurs in the context of a different claim.” Thus, the fact that ALJ Gulin and ALJ Kelton’s decisions concern claims for different months is of no moment, because the issue is whether TTFT is a Medicare covered treatment for Mr. Banks. There is no reference in either Order to indicate that a basis of the Order hinged upon the particular months in question.

Indeed, the very purpose of collateral estoppel in avoiding inconsistent results is illustrated in this case. As noted, ALJ Gulin and Kelton’s decisions cover alternating months with the following results:

January 2018	Treatment Not Covered (ALJ Kelton)
February 2018	Treatment Covered (ALJ Gulin)
March 2018	Treatment Not Covered (ALJ Kelton)

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<sup>7</sup> Subsumed in the determination of whether something is a Medicare covered benefit is the issue of whether it is “medically reasonable and necessary.” ALJ Gulin found that TTFT was “medically reasonable and necessary for Mr. Banks. *See* CAR1279 (“The service is medically reasonable and necessary ...”). By contrast, ALJ Kelton held that it was not. *See* CAR1261.

April 2018	Treatment Not Covered (ALJ Kelton)
May 2018-January 2019	Treatment Covered (ALJ Gulin)

Avoiding non-sensical results like this is one purpose of collateral estoppel. *Allen*, 449 U.S. at 94; *Parklane*, 439 U.S. 326.

Further, the fact that ALJ Gulin’s decision issued three days after the decision of ALJ Kelton is no bar to the application of collateral estoppel. Because the Secretary did not appeal the decision in Mr. Bank’s favor, ALJ Gulin’s decision has become final. By contrast, ALJ Kelton’s decision is not final because it is the object of this appeal. As noted by the Supreme Court in *Elder*, where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect in the still pending case. *Elder*, 270 U.S. at 615-16.

Here, ALJ Gulin’s decision reached finality before ALJ Kelton’s and, therefore, should have preclusive effect.

### **C. The Issue Was Actually Litigated in the Prior Proceeding**

As noted by the Eleventh Circuit in *Christo*: “[W]hen an issue is properly raised, by the pleadings or otherwise, and is submitted for determination, and is determined, the issue is actually litigated.” *Christo*, 223 F.3d at 1339 (internal quotations omitted, citing RESTATEMENT (SECOND) OF JUDGMENTS § 27 cmt. d (1982)).

In the present case, Mr. Banks sought Medicare coverage for his TTFT treatments. *See* CAR1273 (“E. Banks ... seek[s] coverage for tumor treatment filed [sic] therapy provided on the Dates of Service.”). Mr. Banks properly raised the issue of Medicare TTFT coverage for himself by appealing the negative decision of the QIC. *See* CAR1273 (“The QIC issued unfavorable reconsideration decisions[.] [Mr. Banks] filed a timely request for an Administrative Law Judge ...”).

Further, ALJ Gulin actually determined that issue in rendering his favorable decision. *See* CAR1279 which provides:

[T]here is sufficient evidence supporting the Elec. Stim. Cancer Treatment (E0766) provided on the dates of service meets Medicare Coverage criteria. The service was medically reasonable and necessary as required by Section 1862(a)(1)(A) of the Act and the Appellant is entitled to Medicare coverage.

Thus, the issue of Medicare coverage for Mr. Banks TTFT treatment/whether it is “medically reasonable and necessary” was actually litigated before ALJ Gulin.

**D. The Determination in the Prior Litigation Was a Critical and Necessary Part of the Judgment**

Of course, the issue being litigated in ALJ Gulin's decision was whether TTFT is a Medicare covered benefit/is "medically reasonable and necessary" for Mr. Banks. *See* CAR1273 ("E. Banks ... seek[s] coverage for tumor treatment filed [sic] therapy provided on the Dates of Service."). Given that it is the determinative issue, the decision on it is a critical and necessary part of ALJ Gulin's judgment. *See* CAR1279. Likewise, because something is a Medicare covered benefit only if it is "medically reasonable and necessary", that determination was critical and necessary to ALJ Gulin's judgment.

**E. The Secretary Had a Full and Fair Opportunity to Litigate**

As noted by another court in this Circuit:

Notice and opportunity to participate, attend, and present is the foundation of due process and the "full and fair opportunity to litigate" element.

*In re: Jones*, 611 B.R. 685, 698-99 (M.D. Ala. 2020) (quoting and citing *Mullane v. Cent. Hanover Bank & Tr. Co.*, 339 U.S. 306, 314 (1950)).

Mr. Banks was represented by Parrish Law Offices in the proceedings before ALJ Gulin. *See* CAR1273 ("Attorney Debra Parrish provided argument for the Appellant."). Accordingly, pursuant to the Secretary's regulations set forth above, the Secretary had the full panoply of litigation rights. The Secretary could have objected to the timing of the hearing, objected to the ALJ, conducted discovery,

called witnesses, submitted briefs, etc. The Secretary did none of that and did not appear at the hearing.

The proceedings before ALJ Gulin were proceedings before the Secretary himself and he obviously has notice of the proceedings that he conducts.

Nevertheless, out of an abundance of caution, Mr. Banks addresses the notice procedures employed by ALJ Gulin. ALJ Gulin sent three notices of the hearing to the Secretary's designated representative (MAXIMUS). *See* Office of Medicare Hearings and Appeals Case Processing Manual, Chap. 14, 14.0, n. 63 ("CMS has designated the AdQIC to receive notices of hearing in Part A and Part B appeals of QIC reconsiderations", citing 42 C.F.R. § 405.1020(c)(1)). Thus, the Secretary was provided with this additional notice of the hearing conducted by ALJ Gulin. *See* Exhibits A-2 through A-4.

Finally, again as set forth above and pursuant to 42 C.F.R §§ 405.1100-1140 or 405.1110, the Secretary could have appealed ALJ Gulin's decision. Again, the Secretary did not and ALJ Gulin's decision became final.

The Secretary had a full and fair opportunity to litigate the issues in the proceedings before ALJ Gulin.

## V. CONCLUSION

Mr. Banks sustained his burden in proving that TTFT is a Medicare covered benefit for him/is “medically reasonable and necessary” and the Secretary allowed that decision to become final. Out of simple fairness and consistent with the very purposes of collateral estoppel, the Secretary should be estopped from denying coverage and forcing Mr. Banks to bear the cost, delay, and uncertainty of repeated litigation.

This is a time that Mr. Banks should be spending with his family, not repeatedly litigating this issue of whether he can receive the life-extending treatment for his deadly form of brain cancer.

**THEREFORE**, Mr. Banks respectfully asks this Court to enter an Order granting Mr. Banks’ Motion for Summary Judgment and, pursuant to 42 U.S.C. § 405(g) (fourth sentence), remand this matter to the Secretary with instruction to cover Mr. Bank’s claim.

/s/Robert R. Baugh  
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**CERTIFICATE OF SERVICE**

I hereby certify that on May 14, 2020 I filed the foregoing with the Clerk of Court via the CM/ECF electronic filing system which will send electronic notice of the foregoing pleadings to all counsel of record.

/s/ Robert R. Baugh  
OF COUNSEL